

Atty. Dkt. No. 029318-0976

ITED STATES PATENT AND TRADEMARK OFFICE

Ray W. WOOD et al. Applicants:

Title:

NANOPARTICULATE BECLOMETHASONE

COMPOSITIONS (AS AMENDED)

Appl. No.:

10/667,472

Filing Date: 09/23/2003

Examiner:

Unassigned

Art Unit:

1616

INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR §1.56**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the communication from a foreign patent office.

RELEVANCE OF EACH DOCUMENT

Any document listed on the attached PTO/SB/08 was cited in a Notice of Opposition filed in connection with the corresponding European application. An English-language translation of the foreign-language documents is not readily available. The absence of a translation or an English-language counterpart document does not relieve the PTO from its duty to consider any submitted document (37 CFR §1.98 and MPEP§609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

FOLEY & LARDNER LLP

Date/1/ay 18, 2005

Customer Number: 22428

Telephone:

(202) 672-5538

Facsimile:

(202) 672-5399

Michele M. Simkin

Attorney for Applicants

By Midule M. M. Mu

Registration No. 34,717

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

number.						
Substitute for form 1449B/PTO				Complete if Known		
	INFORMATIO	N DISCLOSURE	PE	Application Number	10/667,472	
		BY APPLICAND	· C&	Mrining Date	09/23/2003	
		<i>(</i>)	A William	First Named Inventor	Ray W. Wood	
		1	M J B TO	Group Art Unit	1616	
	(use as many sh	neets as necessar		Examiner Name	Unassigned	·
Sheet	1	of 13%	Æ	Attorney Docket Number	029318-0976	

U.S. PATENT DOCUMENTS							
Examiner Initials*		U.S. Patent Document		No. of Detector of Applicant of	Date of Publication of	Pages, Columns, Lines, Where Relevant	
	Cite No. ¹	Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	
					.,		

				FC	REIGN PATENT DOCUMEN	TS		
Examiner Initials*	Cite No.1	Foreign Patent Document Office ³ Number ⁴ Kind Code ⁵ (if known)		Kind Code ⁵	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	∓ 6
	A1	wo	92/18105	A1	SANDOZ LTD.	10/29/1992		17

		NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	The Mam Many manazine intimat spilat syttibusitiff catalog, etc. / date, bage(3), voidine 1999 intimates			
	A2	KIRBY ET AL., "Liposomes," Encylopedia of Controlled Drug Delivery, Vol. 1, John Wiley & Sons, 1999, pp. 461-473.			
	А3	VOIGHT, <i>Pharmazeutische Technologie</i> , 7 th Edition, Ullstein Mosby, 1993, pp. 181-182.			
	A4	STRICKER (Ed.), <i>Physikalische Pharmazie</i> , 3 rd Edition, Wissenschaftliche Verlagsgesellschaft Stuttgart, 1987, pp. 27-28.			
	A5	CRAIG ET AL., "The relevance of the amorphous state to pharmaceutical dosage forms: glassy drugs and freeze dried systems," <i>International Journal of Pharmaceutics</i> , 179(1999), pp. 179-207.			
			1,3,1		
			14 7		

	D-1-]
Examiner	Date	
Examiner Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.